



BIOCARDIA[®]

Developing cellular and cell-derived therapeutics for the treatment of cardiovascular and pulmonary diseases

Corporate Presentation
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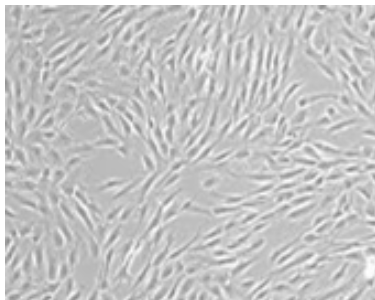
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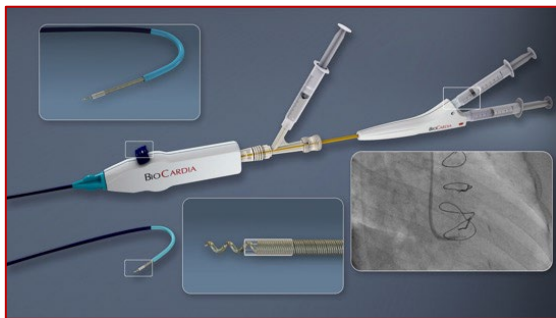
Proprietary Platforms Overview



- CardiAMP® Autologous Mononuclear Cells - lead program for ischemic heart failure of reduced ejection fraction (HFrEF), second program for related indication of chronic myocardial ischemia



- Pipeline-in-a-Product: Off the Shelf MSC Therapies - Advancing CardiALLO™ and PulmAllo, and offering clinical grade MSC and their exosomes for partnering in many other indications enhanced by extensive freedom to operate.



- Pipeline-in-a-Product: Local Delivery to the Heart - Transendocardial catheter-based local delivery technologies for cell, gene, and protein based therapies to treat cardiac indications.

Therapeutic Product Pipeline

Resulting from Platforms

Therapeutic Platform	Candidate	Preclinical	Phase 1	Phase 2	Phase 3
Autologous Mononuclear Cells	CardiAMP® HF BCDA-01 ^{α, β, Δ}	Ischemic Heart Failure with Reduced Ejection Fraction (HFrEF)			
	CardiAMP® CMI BCDA-02 ^{β, Δ}	Chronic Myocardial Ischemia with Refractory Angina			
Allogeneic Mesenchymal Stem Cells	CardiALLO™ HF BCDA-03 ^ψ	Ischemic HFrEF			
	PulmALLO™ ARDS BCDA-04 ^ψ	Acute Respiratory Distress Syndrome	IND approved but not active.		

α = FDA Breakthrough Designation

β = Reimbursed by Center for Medicare and Medicaid Services

Δ = Regulated by CBER through IDE/PMS Pathway in USA

ψ = Regulated by CBER through IND/BLA Pathway in USA

BIOCARDIA®

Problem: Heart failure, a disease with enormous unmet need

- 56.2 million people worldwide have HF. ¹
- In the United States, HF costs are projected to increase to \$70 billion in 2030, half related to hospitalization. ¹
- In Japan, one million patients have heart failure with 31 to 47% having ischemic etiology² and it is considered a national priority.
- Despite guideline directed medical therapy:
 - High mortality: 50% mortality at five years³
 - Frequent hospitalizations
 - Significant quality of life impairment
- No therapies directly address myocardial microvascular dysfunction and its impact on adverse remodeling.

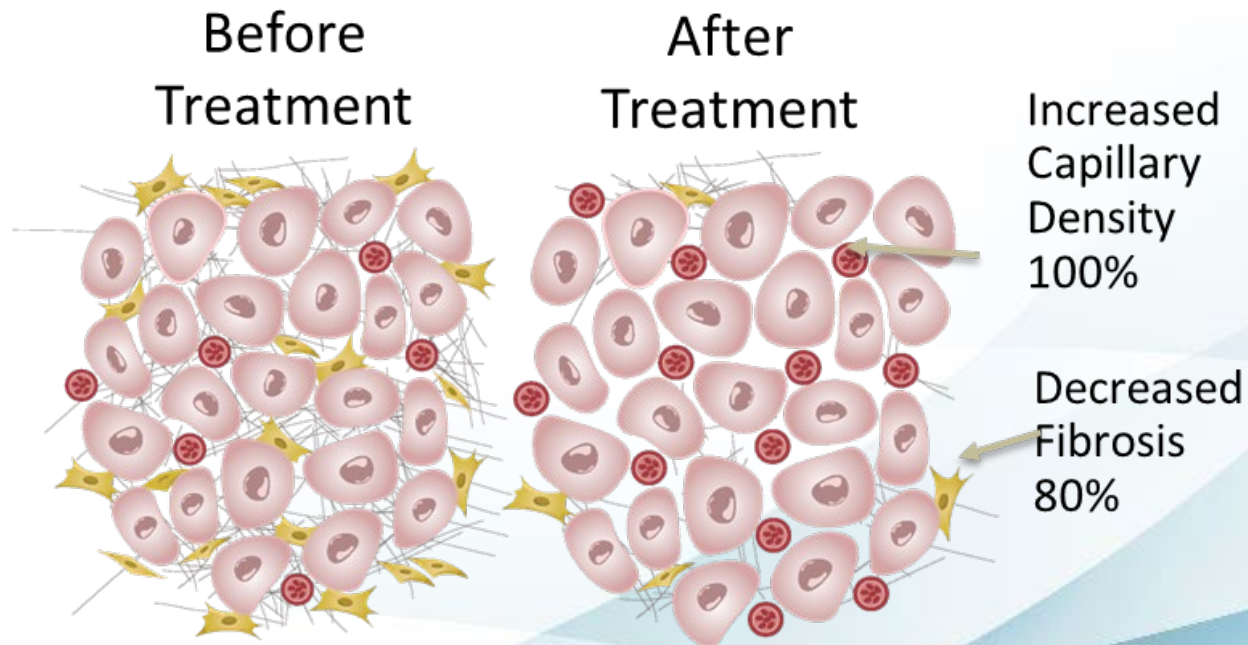


Sources of data:

1. Martin et al 2024 Heart disease and statistics from the American Heart Association
2. Heart failure epidemiology and novel treatments in Japan: facts and numbers Masaaki Konishi, European Heart Journal 2016.,
3. EMPOROR -Reduced Trial, NEJM, 2020.

Potential Solution: Enhancing Microvascular Function

- New mechanism of action:
 - improve microvascular capillary density
 - reduce fibrosis
 - prevent adverse remodeling
- Mechanism driven primarily by cell mediated paracrine signaling
- Not intended to regenerate new myocardium



Silva et al. Tex Heart Inst J (2011);38(3):219-24.

Takahashi, M. et al. (2006) Am J Physiol Heart Circ 291:H886-H893.

CardiAMP® Cell Therapy: Lead Program

FDA Breakthrough Designation / Has CMS Reimbursement

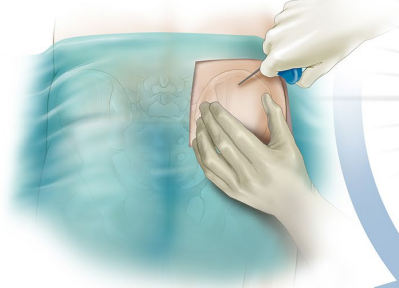
Autologous Cell Therapy For ischemic HFrEF

Pre-procedure Screening

Small amount of bone marrow collected from hipbone and sent to lab for testing

1 Cell Collection

Small amount of bone marrow obtained from hipbone
~ 20 minutes



2 Cell Processing

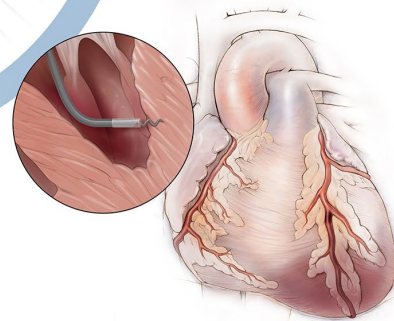
Bone marrow cells prepared for transfer at point of care
~ 25 minutes



CardiAMP™ Therapy

3 Cell Delivery

Bone marrow cells injected into damaged heart tissue through a catheter-based procedure
~30 to 45 minutes



Post-procedure

Patient leaves hospital the next day



04142-C (MKT)

CardiAMP System Development Status

200 Procedures and Counting



FDA Breakthrough Device Designation granted based on results from Phase I and II trials.



CMS Reimbursement Code C9782 for CardiAMP Cell Therapy for both treated and control patients at \$20,000 (\$35,000 for a treatment and a control)

**TABMMI Ph I
Cell Therapy Trial**

Open label clinical trial on 20 patients (NCT00507468) ¹

- Safety, Early Efficacy

**TAC-HFT Ph II
Cell Therapy Trial**

Double-blind controlled clinical trial in 33 patients (NCT00768066) ^{2,3}

- Safety and Efficacy signals

**CardiAMP HF Ph III
Cell Therapy Trial**

Double-blind controlled clinical trial in 125 patients (NCT02438306) ^{4,5}

- Efficacy in patients having elevated biomarkers of heart stress (NTproBNP)



Japan's Pharmaceutical and Medical Device Agency has indicated that this clinical data is likely sufficient for regulatory approval.

**CardiAMP HF 2 Ph III
Cell Therapy Trial**

Actively enrolling in USA at four centers.

1. De la Fuente, Eurointervention 2011,
2. Wong Po Foo WCRM 2015,
3. Heldman JAMA 2014.
4. Raval ACC 2025.
5. Raval THT 2026.

Phase III CardiAMP HF Trial

Autologous intramyocardial bone marrow mononuclear cell (MNC) therapy was safe but did not meet its primary composite endpoint, though patients with elevated NT-proBNP/BNP showed signals of benefit.



- The largest randomized, double-blind trial to date evaluating high-dose autologous bone marrow mononuclear cells delivered percutaneously for ischemic HFrEF
- Uniquely incorporated a proprietary cell population analysis (CPA) to select patients for sufficient CD34+ cell content
- Provides rare, blinded, core-lab adjudicated, long-term (24 month) data on LV remodeling after autologous cell therapy

PRIMARY ENDPOINT

3-tier composite outcome



Tier 1: All-cause death, heart transplant, LVAD



Tier 2: Non-fatal major adverse cardiovascular events (MACE)



Tier 3: Change from baseline

PRIMARY: Effort capacity, 6MWD

KEY SECONDARY: Quality of life, Minnesota Living with Heart Failure Questionnaire (MLHFQ)

TRIAL DESIGN



Multicenter



Double-blind



Randomized 3 to MNC therap or sham contr



115 patients (planned 250)



Followed for 24 months

POPULATION

- Chronic ischemic HFrE
- NYHA II-III
- LVEF 20-40%
- 6-minute walk distance (6MWD) 150-450m
- CPA to select patients for favorable cell characteristics

RESULTS

PRIMARY OUTCOME: No difference between groups (WR=-.99, p=0.96) using 6MWD as Tier 3

KEY SECONDARY OUTCOME: WR=1.42, p=0.13, using MLHFQ as Tier 3

■ TREATMENT GROUP

■ CONTROL GROUP

Overall

Tier 1

14% 17%

Tier 2

11% 20%

Tier 3

6MWD*

+5.7m +24.1m

MLHFQ

Nominal 5.5 point improvement in treatment group (WR=1.42)

* wide variability contributed to neutral endpoint

NT-proBNP/BNP subgroup

Tier 1

14% 27%

Tier 2

17% 27%

Tier 3

6MWD

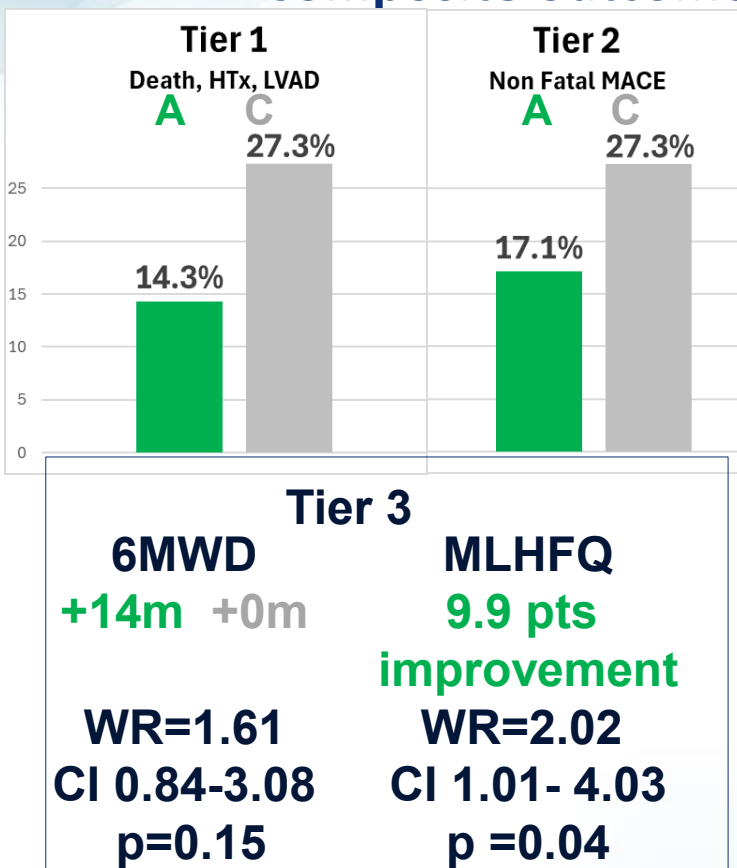
+14m +0m

MLHFQ

9.9 point improvement in the treatment group (WR=2.02)

CardiAMP HF Phase III Results in Patients with NTproBNP/BNP >500 pg/ml

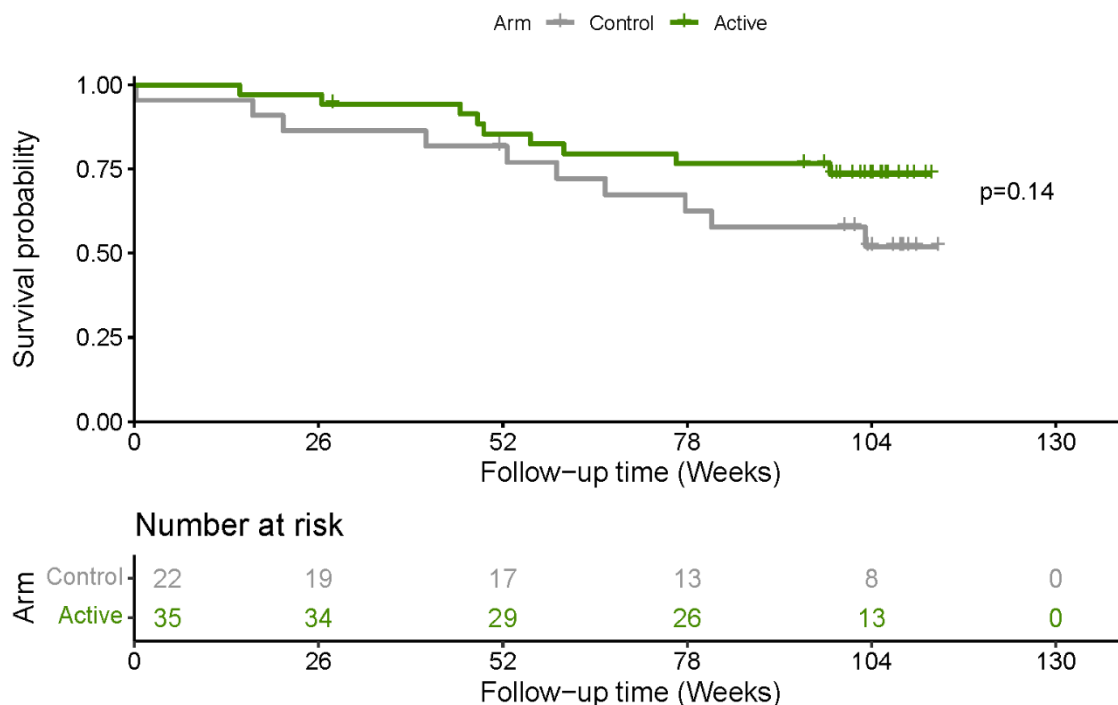
Composite outcome of three tiers – all benefit treatment



A = Active treatment group

C = control placebo procedure group

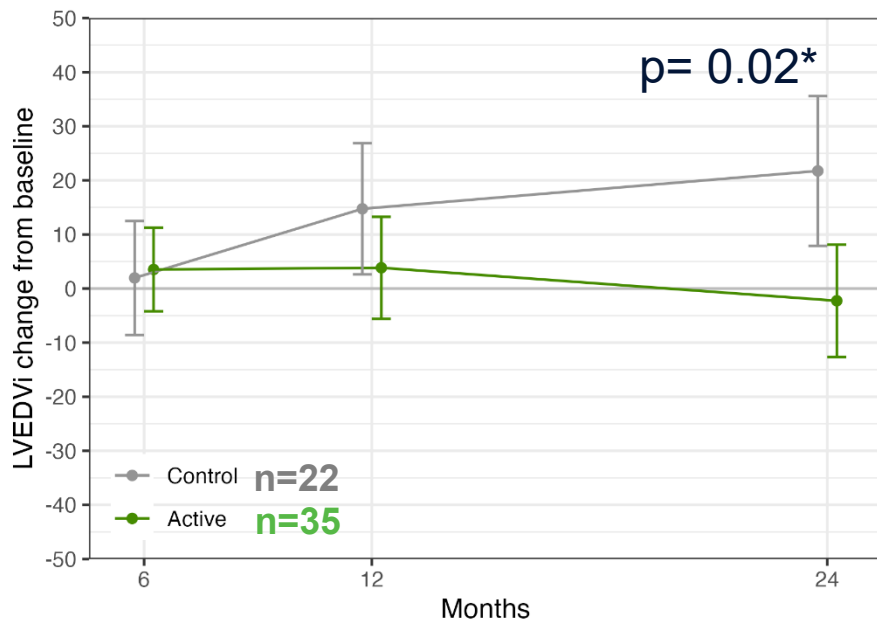
MACE Free Survival: NTproBNP/BNP >500 pg/ml Subgroup



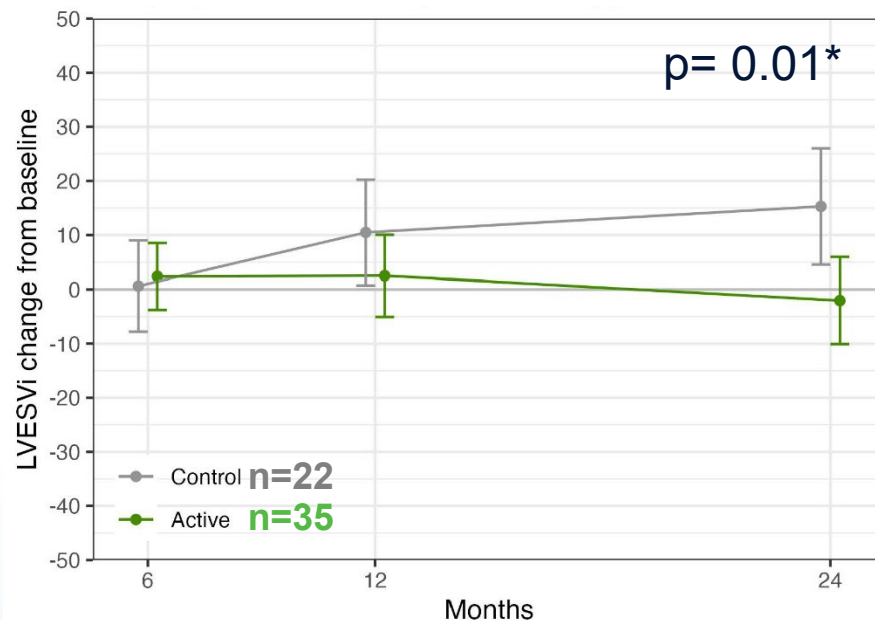
HTx = Heart Transplant; LVAD = Left ventricular Assist Device; MACE = Major Adverse Cardiac Event; 6MWD = six minute walk distance ; MLHFQ = Minnesota Living with Heart Failure Quality of Life; WR = Win Ratio ; CI = Confidence Interval; NTproBNP = Biomarker of heart stress

CardiAMP HF Phase III Results in Patients with NTproBNP/BNP >500 pg/ml
Left Ventricular End Diastolic Volume Index (LVEDVi) and Left Ventricular End Diastolic Volume Index (LVESVi) show prevention of negative heart enlargement. This has long been known to align with positive outcomes.**

LVEDVi



LVESVi



** Kramer DG et al Quantitative Evaluation of Drug or Device Effects on Ventricular Remodeling as Predictors of Therapeutic Effects on Mortality in Patients With Heart Failure and Reduced Ejection Fraction: a Meta-analytic Approach JACC 2010

CardiAMP Key clinical insights

- **Benefit seen across patients in three trials***

- Reduced mortality and non-fatal major adverse cardiac events
- Improved heart function
- Improved quality of life

- **Heart failure patients are heterogeneous**

Analysis suggests greater benefit in patients with both high concentrations of important cell types and evidence of active heart stress.

- Proprietary patient Cell Population Analysis (CPA) may be used to define dosages
- Biomarkers for heart stress (NTproBNP) identify responder population

- **Strategic direction**

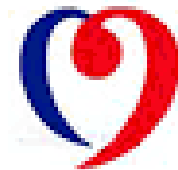
- Focus on precision-defined patient populations

* Details on clinical trial results provided on website and manuscripts available on request.

CardiAMP HF Pathways to Approval and Reimbursement

JAPAN

- **Japan Pharmaceutical and Medical Devices Agency (PMDA) has said they are likely to accept existing evidence of safety and efficacy as sufficient for market release.**
 - Initial indication identical to CardiAMP HF Trial with elevated NTproBNP.
 - PMDA Submission ~ in Q4 2026
 - Approval ~12 months after submission.
 - Initial CardiAMP indication ~20,000 patients / year
 - Post marketing study with CV societies (with reimbursement)



**Japan
Heart Failure
Society**



**Japanese
Circulation
Society**



**Cardiovascular
Interventional
Therapeutics
(CVIT)**

CardiAMP HF Pathways to Approval and Reimbursement

JAPAN

■ Target initial population for CardiAMP cell therapy

- In Japan, total ischemic HFrEF patients are ~ 300,000 and anticipate ~20,000 initial reachable patients with unmet need as discussed with PMDA. A cardiac cell therapy patch that is surgically implanted is now reimbursed at \$326,000 as of July 2026.
- In Japan, there is potential to exceed ramp of transcatheter aortic valve replacement (TAVR) cases which rose from 925 to 7,778 in 5 years, exceeding the growth rate of TAVR in the USA over the same period. The number of hospitals performing TAVR increased drastically from 15 to 170 in the same period. TAVR competed with surgical valve replacement. CardiAMP addresses unmet clinical need.

Tentative timelines with Post Marketing Surveillance Studies (PMSS)

	2026	2027	2028	2029
Japan	Submission	Approval	Commercial/PMS	Commercial/PMSS

1. Kaneko T, et al. Practice Patterns and Outcomes of Transcatheter Aortic Valve Replacement in the United States and Japan: A Report From Joint Data Harmonization Initiative of STS/ACC TVT and J-TVT. J Am Heart Assoc. 2022 Mar 15;11(6):e023848.

CardiAMP HF Pathways to Approval and Reimbursement USA

- Target initial population for CardiAMP cell therapy
 - Patients with ischemic heart failure, on guideline directed medical therapy but still having biomarker evidence of active heart stress ~ 1 million patients in USA ^{1, 2}
 - Reimbursement in USA is currently \$20,000 per treated patient, while investigational.
- FDA Breakthrough Designation
- FDA has said actively enrolling CardiAMP HF II Trial may be sufficient for a successful Premarket Application (PMA) submission.

1. Martin et al 2024 Heart disease and statistics from the American Heart Association
2. Vedin 2017 Significance of Ischemic Heart Disease in Patients With Heart Failure and Preserved, Midrange, and Reduced Ejection Fraction

Ongoing Confirmatory CardiAMP HF II Clinical Trial

- Double Blind Procedure Placebo Controlled Randomized (1:1) Trial (NCT06258447)
 - NYHA Class II and III, EF < 40%, Ischemic etiology, with elevated NTproBNP
 - Patients on stable Guideline Directed Medical Therapy
 - One month screening to baseline delay to address Hawthorne Effect
 - Finkelstein Schoenfeld composite endpoint including: Mortality, Major adverse cardiac events, Quality of life measures
 - Power of 80% with 160 patients
 - Up to 250 patients at up to 40 centers
 - 4 World Class centers activated and enrolling



2nd Platform

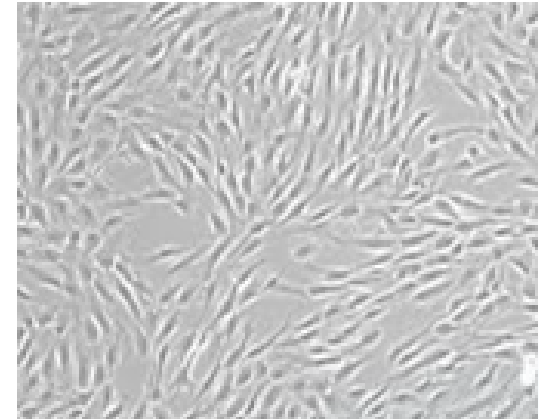
Allogeneic Mesenchymal Stem Cells

being advanced for
Cardiac and Pulmonary indications

CardiALLO Allogeneic Cell Therapy Strategic Optionality

Pipeline-in-a-Product: Off the Shelf MSC Therapies

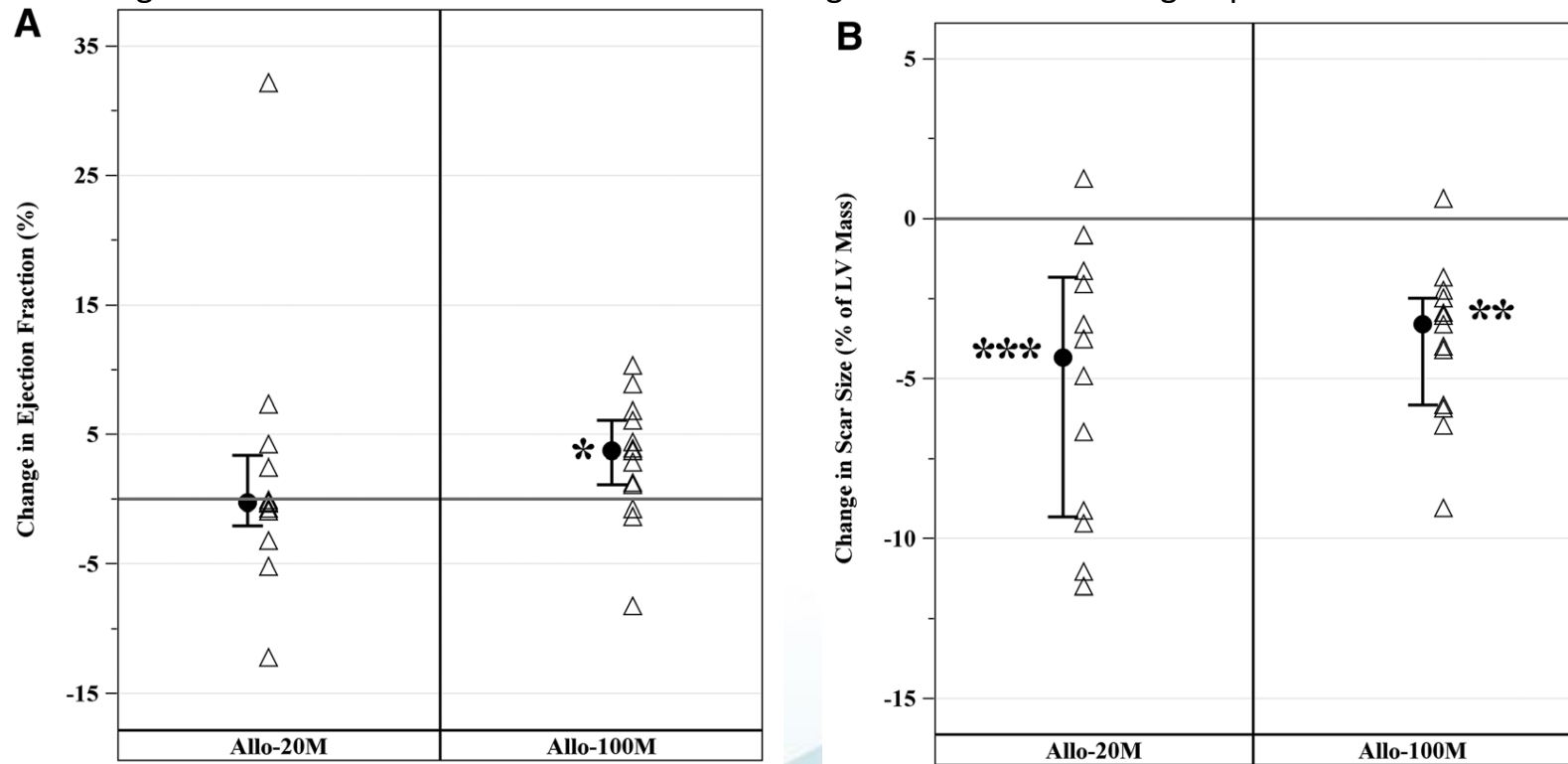
- Donor derived mesenchymal cells manufactured and cryopreserved for therapy
 - Potential advantages
 - Off the shelf availability – reduces clinical procedural logistics
 - No need for performing a tissue collection on treatment day
 - Limits patient to patient variation of therapy
 - Single donor creates a cell bank for multiple patients.
 - Clinical development focused on safety and biological activity
 - 48 Patients treated in three trials to date – all with positive results



Allogeneic Mesenchymal Stem Cells in Heart Failure (BCDA-03) Phase I/II TRIDENT Clinical Study, NCT02013674

Allogeneic MSC at 20M and 100M cells (N= 30) delivered at ten sites with Helix. Primary outcome measures: thirty-day post catheterization incidence of predefined treatment-emergent serious adverse events (SAEs) showed no safety issues.

Efficacy assessments demonstrated Improvement in heart function as measured by left ventricular ejection fraction at higher dose and reduced scar size in both the high dose and low dose groups.



Florea V, et al. Dose Comparison Study of Allogeneic Mesenchymal Stem Cells in Patients With Ischemic Cardiomyopathy (The TRIDENT Study). Circ Res. 2017 Nov 10;121(11):1279-1290.

3rd Platform

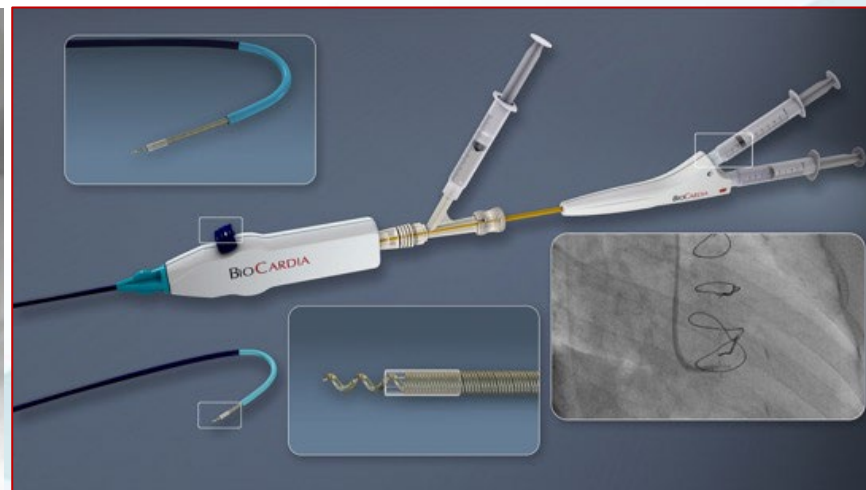
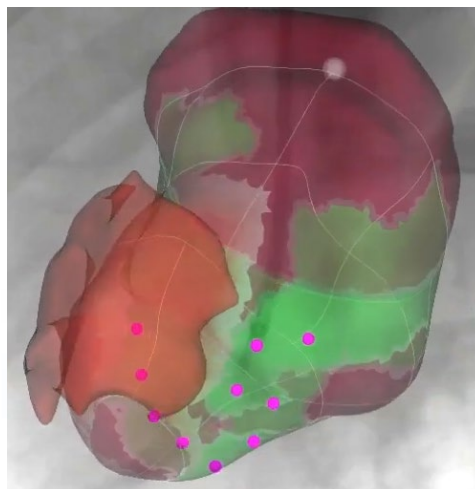
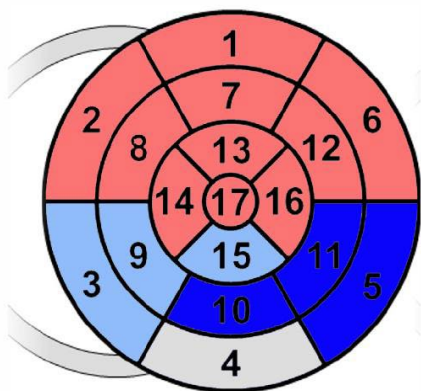
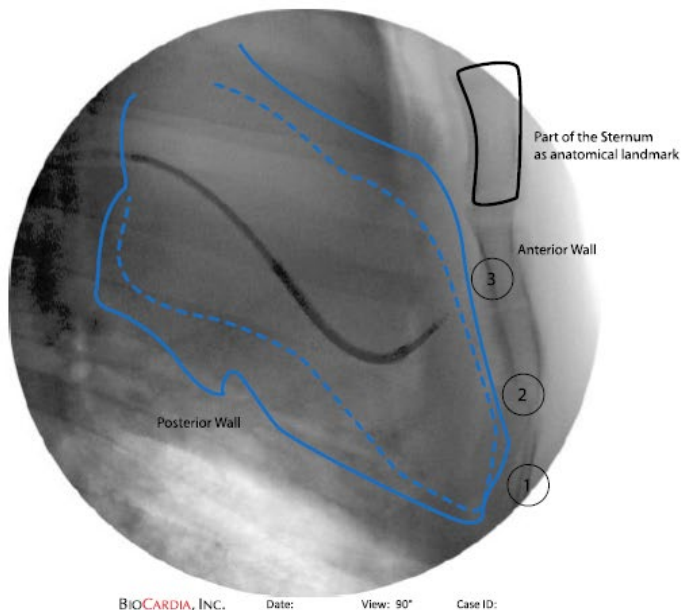
Helix cardiac biotherapeutic delivery
for cell, gene, and protein delivery to the heart

Delivery as a Differentiator

Pipeline-in-a-Product: Local Delivery to the Heart

Precision Transendocardial Delivery

- Proprietary catheter-based delivery systems
- Designed for targeted myocardial injection
- Delivery quality recognized as a key variable in cardiac cell therapy outcomes
- DeNovo Approval Pathway Possible based on May 2026 FDA PreSub.



BioCARDIA®

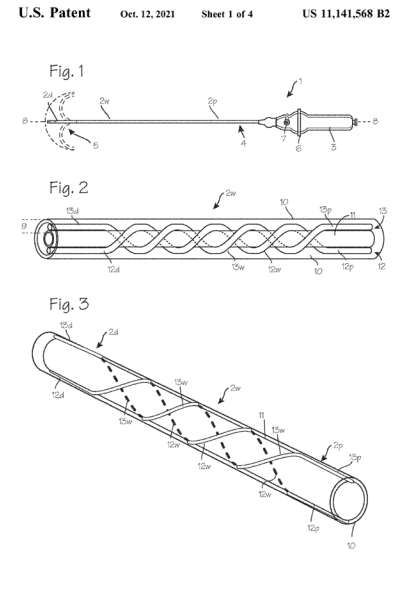
Intellectual Property Overview

- Exclusive rights to over 60 patents and patent applications in USA, Europe, China, India, and Japan with goal to protect the company's platform and therapeutic initiatives.

	
(12) United States Patent de la Fuente et al.	
(14) Patent No.: US 9,517,199 B2	(45) Date of Patent: *Dec. 13, 2016
FOREIGN PATENT DOCUMENTS (71) Applicant: BioCardia, Inc. , San Carlos, CA (US) (72) Inventors: Luis M. de la Fuente , Buenos Aires (AR); Shawn R. Sharkey , Santa Fe, NM (US); Julio Argenteiro , Buenos Aires (AR); Edurne Pedraza , Buenos Aires (AR); Peter A. Altman , Menlo Park, CA (US) (73) Assignee: BioCardia, Inc. , San Carlos, CA (US) (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 73 days. This patent is subject to a terminal disclaimer. (21) Appl. No.: 14/030,305 (22) Filed: Feb. 24, 2015 (65) Prior Publication Data US 2015/0164736 A1 Jun. 18, 2015 Related U.S. Application Data (63) Continuation of application No. 13/953,961, filed on Jul. 30, 2013, which is a continuation of application No. 11/775,869, filed on Apr. 16, 2007; now Pat. No. 6,495,025. (51) Int. Cl.: A61M 61/00 (2006.01); A61M 5/28 (2015.01); A61M 5/34 (2015.01); A61M 5/32 (2015.01); A61M 5/35 (2015.01) (52) U.S. Cl.: CPC (53) Field of Classification Search See application file for complete search history. (56) References Cited U.S. PATENT DOCUMENTS 6,585,716 B2 7/2003 Altman 6,878,331 B2 7/2005 Freyman 7,296,349 B2 9/2010 Uno et al. 8,006,026 B2 7/2012 De La Fuente et al. 8,006,012 B2 7/2012 Uno et al. 2004/0115181 A1 7/2004 Inoue 2009/0144411 A1 5/2009 Kurokawa et al. 2009/0144411 A1 5/2009 De La Fuente et al. 2013/0023112 A1 12/2013 De La Fuente et al.	

	
(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT) (19) World Intellectual Property Organization (43) International Publication Date 02 April 2020 (02.04.2020)	
(11) International Publication Number WO 2020/069215 A1	
(51) International Patent Classification: A61M 5/32 (2013.01) A61M 5/28 (2006.01) A61M 5/34 (2015.01) A61M 5/35 (2015.01) (21) International Application Number: PCT/US2019/053293 (22) International Filing Date: 26 September 2019 (26.09.2019) (23) Filing Language: English (24) Priority Language: English (30) Priority Data: 62/777,627 27 September 2018 (27.09.2018) US (71) Applicant: BIOCARDIA, INC. , 125 Shoreway, Suite B, San Carlos, California 94070 (US) (72) Inventors: MCNICHIE, Ian , 125 Shoreway, Suite B, San Carlos, California 94070 (US); ALTMAN, Peter , 125 Shoreway, Suite B, San Carlos, California 94070 (US) (74) Agent: GRANT, EVIN , Wilson Sonnet Goodrich & Rosati, 610 Page Mill Road, Palo Alto, California 94304 (US) (54) Title: BONE MARROW DERIVED NEUROKININ-1 RECEPTOR POSITIVE (NK1R+) PRECURSOR CELLS FOR THERAPEUTIC APPLICATIONS (57) Abstract: A method of treating chronic post-myocardial infarction including infusing autologous bone marrow derived neurokinin-1 receptor positive (NK1R+) precursor cells into the infarcted region of the heart. The method includes: (a) identifying a patient with chronic post-myocardial infarction; (b) obtaining autologous bone marrow from the patient; (c) isolating NK1R+ precursor cells from the autologous bone marrow; (d) culturing the NK1R+ precursor cells; and (e) infusing the cultured NK1R+ precursor cells into the infarcted region of the heart.	

	
(12) United States Patent Application Publication Hsieh et al.	
(14) Pub. No.: US 2020/0398029 A1	(45) Pub. Date: Dec. 24, 2020
Publication Classification (51) Int. Cl.: A61M 25/00 (2006.01); A61M 25/09 (2006.01); A61M 25/00 (2006.01) (52) U.S. Cl.: CPC (53) Field of Classification Search See application file for complete search history. (56) References Cited U.S. PATENT DOCUMENTS 6,585,716 B2 7/2003 Altman 6,878,331 B2 7/2005 Freyman 7,296,349 B2 9/2010 Uno et al. 8,006,026 B2 7/2012 De La Fuente et al. 8,006,012 B2 7/2012 Uno et al. 2004/0115181 A1 7/2004 Inoue 2009/0144411 A1 5/2009 Kurokawa et al. 2009/0144411 A1 5/2009 De La Fuente et al. 2013/0023112 A1 12/2013 De La Fuente et al.	



Executive Management Team

			
Peter Altman	David McClung	Debby Holmes-Higgin	Edward Gillis
CEO	CFO	VP Clinical	SVP Devices



Board of Directors:

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- Bill Facteau, CEO Earlens, Board member Aerin Medical
- Jim Allen, CEO United Toll Systems, LLC.

Financial Data and Significant Anticipated Catalysts

	Year Ended 2023 (\$ mm)	Year Ended 2024 (\$mm)	Year Ended 2025 (\$mm)
Net Loss	\$11.6	\$7.9	\$8.2
Cash used in operations	\$10.0	\$8.0	\$7.4
Cash & Equivalents	\$1.1	\$2.4	\$2.5
Debt	N/A	N/A	N/A

15.0 M shares of common stock issued and outstanding.

7.9 M Warrants outstanding at weighted average of \$1.88 strike price.

CardiAMP Cell Therapy

Q4 '26 Peer Reviewed Manuscript
Q4 '26 Japan PMDA Submission for Approval
Q4 '27 Japan Approval
Q3 '28 HF II completes enrollment
Q3 '29 HF II Topline Data

Helix Delivery

Q3 '26 FDA Pre-Sub Amendment

Heart3D Fusion Imaging

Q1'27 First in Man

No milestones on CardiALLO platform or Morph DNA platform are being detailed at this time.

NASDAQ: BCDA

BIOCARDIA®